510(K) Summary

DEC - 2 2010

Subject 510(k) Number: K101126

Sponsor

Core Essence Orthopaedics, Inc
575A Virginia Drive
Fort Washington, PA 19034

FDA Establishment Registration Number
3004613836

Official Contact

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Proprietary Name

1. **PONTiS™ Sutures and Suture Anchors with Optional Crimps**

Common Name

1. Suture Anchor, Stainless Steel Suture

Regulatory Class & Device Product Codes, Suture Anchors

Class II 21 CFR § 888.3040 Smooth or threaded metallic bone fixation fastener
Class II 21 CFR § 878.4495 Suture, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile

Product Codes (Panel 87, Orthopedic):

PONTiS™ Suture Anchor with optional crimp

- **MBI** (fastener, fixation, nondegradable, soft tissue)

Date Prepared: November 26, 2010

PONTiS™ Sutures with optional crimp

- **GAQ**

The substantial equivalence of the **PONTiS™** families of sutures and crimp collars is based on the equivalence in intended use, materials, operational principals, and indications to other metallic sutures or cables secured with a crimp, including the Core Essence PONTiS™ ferroFibre stainless steel suture (K081060), the Pioneer Surgical SDB Cerclage System (K992616), the Ortheon Medical Tenofix tendon repair devices (K023594).

The substantial equivalence of the **PONTiS™** 3.0mm suture anchors are based on the equivalence in intended use, materials, operational principals, and indications to **reNOVO™** and other suture anchors including the Core Essence Orthopaedics reNOVO™ (K071520) and the J&J DePuy Mitek Micro Anchor (K962511).

Brief Description of the Device, Sutures with Crimp Collars

This premarket notification covers line extensions for the **PONTiS™** product line. The **ferroFibre™** stainless steel (SS) sutures were cleared for marketing in 2008, and are marketed in the **PONTiS ™** product group. The **PONTiS™** product family has been expanded to include stainless steel suture anchors geometrically similar to the **reNOVO™** titanium product family (cleared in 2007), in combination with **ferroFibre™** SS Sutures and optional suture crimps.

The **PONTiS ™ implants** incorporate non-absorbable **ferroFibre™** 316 L Stainless Steel Surgical sutures and are available in United States Pharmacopoeia (USP) sizes 4-0 and 3-0 in various lengths.

316L Stainless steel is used in a wide variety of medical devices including previously approved implants of this type. The **ferroFibre™** Stainless Steel Sutures may be secured by either knot tying or crimping with a collar.

The **ferroFibre™** multifilament sutures are supplied sterile, armed with cutting needles.

The implant components also include stainless steel collars specific to each suture size. The collars are used to secure multiple suture strands together simultaneously by crimping. For example, crimps are sized to accept between four (4) and eight (8) strands of each specific size of **ferroFibre™** suture for crimping. A crimping instrument is supplied to crimp the collars to the suture strands. An adjustable tendon holder with suture tensioning slots is provided to facilitate suture cable tightening and tensioning. Excess suture is cut and removed.

Indications for Use

PONTiS™ Sutures with Optional Crimps are indicated to secure soft tissue to soft tissue reattachment in the hand:

- *Collateral Ligaments around the PIP, DIP and MCP Joints*
- *Flexor and Extensor Tendons*

Safety and Performance, PONTiS™ Anchors with ferroFibre™ Sutures and Crimp Collar Securing Method

A collection of tests was conducted to characterize biocompatibility, diameter and tensile strength of the sutures in accordance with:

◊ · ISO 10993 standards
◊ USP 32–NF 26 Monographs <861>, <871>, <881>
◊ Class II Special Control Guidance, Surgical Suture; Guidance for Industry and FDA, June 3, 2003

In addition, a crimped suture loop pull-strength test was developed and used to verify that multiple sutures secured together using a crimped multi-strand collar had sufficient strength to secure a tendon repair. In the performance tests, the **PONTiS™ Sutures** secured with **Crimp Collars** had sufficient strength and exhibited equivalent results to knot-secured suture products currently marketed for hand tendon repair as confirmed by a comparison to knotted sutures and to the literature.

The **Crimp-Collar**-secured multi-strand suture tensile strengths were sufficient to support active motion without resistance following tendon reattachment in the hand.

All materials were subjected to biocompatibility reviews or tests including cytotoxicity, sensitization, and irritation. All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices). The performance studies and biocompatibility reviews indicate that the **PONTiS™ Sutures,** secured with crimped **Collars** are safe for their intended use.

Basis for Substantial Equivalence, Sutures with alternate Crimp Collar securing method:

Core Essence Orthopaedics **PONTiS™ ferroFibre™** sutures secured with crimp collars are substantially equivalent to other sutures currently marketed in conjunction with suture anchors and present no substantial differences in design, material, intended use and function to previously approved products. Additionally, the subject device labeling is consistent both with FDA's guidance as well as current medical practice.

The substantial equivalence of the **PONTiS™** families of sutures and crimp collars is based on the equivalence in intended use, materials, operational principals, and indications to other metallic sutures or cables secured with a crimp, including the Core Essence

PONTiS™ ferroFibre stainless steel suture (K081060), the Pioneer Surgical SDB Cerclage System (K992616), the Ortheon Medical Tenofix tendon repair devices (K023594).

Brief Description of the Device, Suture Anchors

PONTiS™ Suture Anchors

The stainless steel **PONTiS™ Suture Anchors** are 3.0mm in diameter, are self-tapping, and fully threaded. The anchors are each available with 4-0 and 3-0 multi-strand ferroFibre™ stainless steel sutures. A disposable anchor driver holds the excess suture and delivers the anchor directly into the bone. The strands are then used to secure the soft tissue to bone.

Prior to installation, a hole is created in the bone using k-wire, drill or punch. The anchor is threaded into this hole. The anchor has self-tapping flutes.

Unlike the previously cleared titanium **reNOVO™** Suture Anchor, **PONTiS™** Suture Anchors are fully threaded allowing thread fixation in both cancellous and cortical bone.

The shorter overall length of the 3.0mm anchors, when compared to the self-drilling titanium **reNOVO™** anchors, allows use in smaller/thinner bones where a lower profile is needed to achieve results without subsequent tissue injury.

The **PONTiS™** threaded suture anchors are stainless steel to assure compatibility with the stainless steel in the **ferroFibre™** stainless steel multi-strand sutures and the stainless steel crimp collars.

The size of the nonabsorbable stainless steel **ferroFibre™** sutures used in the **PONTiS™** Anchors is USP 4-0 and 3-0.

A single use driver and hand piece holds the excess suture and delivers the preloaded anchor into the bone. The suture strands are used to reapproximate and secure the soft tissue to bone.

The **PONTiS™ Suture Anchors** are provided sterile for single use applications.

The sizes and materials are designed to address the indications cited.

Indications for Use

PONTiS™ Suture Anchors with Optional Crimps are indicated to secure soft tissue to bone reattachment in the hand:

- *Collateral Ligaments around the PIP, DIP and MCP Joints*
- *Flexor and Extensor Tendons*

Safety and Performance, Suture Anchors

The following safety and performance data has been provided to support substantial equivalence of the **PONTiS™ Suture Anchors** to **reNOVO™** suture anchors.

Performance Testing: The **reNOVO™** and the **PONTiS™ Suture Anchors** were compared in standardized foam bone model materials. The Anchor insertion torque, suture strength (knot pull), pull-out failure mechanism (pull-out or suture break strength) and pull-out failure force were documented. In addition cyclic pull-out performance was characterized. The insertion torque was quantified in hard bone (bovine cortical bone) to assure the integrity of the anchor and anchor driver interface. The suture anchors were also functionally (vs. empirically) evaluated in animal and human cadaver bone by surgeons and engineers. The pullout strengths were sufficient to support active motion without resistance following tendon reattachment in the hand.

In all performance tests the **PONTiS™** Sutures and Anchors secured by knots or crimps exhibited equivalent results to products currently marketed for the same indications as confirmed by a comparison to the literature documenting the comparative characteristics of suture anchors.

All materials were subjected to biocompatibility reviews or tests including cytotoxicity, sensitization, and irritation. The performance studies and biocompatibility reviews indicate that the **PONTiS™ Sutures and Anchors** are safe for their intended use.

Basis for Substantial Equivalence

The substantial equivalence of the **PONTiS™** 3.0mm suture anchors are based on the equivalence in intended use, materials, operational principals, and indications to **reNOVO™** and other suture anchors including the Core Essence Orthopaedics reNOVO™ (K071520) and the J&J DePuy Mitek Micro Anchor (K962511).

Relative to the hand, the **PONTiS™** suture anchors have the same intended use (bone anchoring function), but different technological characteristics than the Mitek Micro-Anchors. (threads vs. barbs). The barbed predicate device from J&J Mitek incorporates the USP 4-0 suture sizes like the **PONTiS™** suture anchors, and is indicated for soft tissue reattachment procedures in the hand.

The 3.0mm **PONTiS™** suture anchors have threaded profiles similar to the 3.0mm **reNOVO™ anchors.** The **PONTiS™** suture anchors are minor modifications of the

original titanium **reNOVO™** anchors, and are indicated for the same procedures in the hand. The **PONTiS™** suture anchors will be sold pre-assembled with stainless steel **ferroFibre™** suture.

Conclusion

The substantial equivalence of the **PONTiS™** families of sutures and crimp collars is based on the equivalence in intended use, materials, operational principals, and indications to other metallic sutures or cables secured with a crimp, including the SBD Cerclage system and the Tenofix tendon repair system.

The Core Essence Orthopaedics **PONTiS™** sutures used in the anchors are substantially equivalent to the previously cleared Core Essence **ferroFibre™** sutures, and the Core Essence Orthopaedics **PONTiS™** suture anchors are substantially equivalent to **reNOVO™** and J&J Mitek Micro-Anchors currently marketed, and present no substantial differences in design, material, intended use and function.

END OF 510K SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Core Essence Orthopaedics, Inc.
% Mr. Jeff Miller
Vice President Operations
575A Virginia Drive
Fort Washington, Pennsylvania 19034

DEC - 2 2010

Re: K101126
Trade/Device Name: PONTis™ Sutures and Suture Anchors with Optional Crimps
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI, GAQ
Dated: November 26, 2010
Received: November 29, 2010

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101126

Statement of Indications for Use

DEC - 2 2010

510 (K) NUMBER IF KNOWN: K101126
MANUFACTURER: Core Essence Orthopaedics, Inc.
DEVICE NAME: **PONTiS™ Sutures and Suture Anchors with Optional Crimps**

PONTiS™ Sutures with Optional Crimps are indicated to secure soft tissue to soft tissue reattachment in the hand:

- *Collateral Ligaments around the PIP, DIP and MCP Joints*
- *Flexor and Extensor Tendons*

PONTiS™ Suture Anchors with Optional Crimps are indicated to secure soft tissue to bone reattachment in the hand:

- *Collateral Ligaments around the PIP, DIP and MCP Joints*
- *Flexor and Extensor Tendons*

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101126

Prescription Use XX (Per 21 CFR 801 Subpart D) **and/or** **Over-the-Counter Use** NO (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)